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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,408	11/03/98	SZKUDLINSKI	M NIH147.001C1

020995 HM12/0324  
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EXAMINER

SPECTOR, L

ART UNIT

PAPER NUMBER

1646

5

DATE MAILED:

03/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file

## Office Action Summary

Application No.	Applicant(s)	
09/185,408	Sztulinska et al.	
Examiner	Group Art Unit	
SPECTOR	1646	

**—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—**

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on 01- SEPTEMBER 1999.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 1-80 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) \_\_\_\_\_ is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) 1-80 are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - All
  - Some\*
  - None
 of the CERTIFIED copies of the priority documents have been
  - received.
  - received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- |  |   |
|--|---|
| <input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ | <input type="checkbox"/> Interview Summary, PTO-413                     |
| <input type="checkbox"/> Notice of References Cited, PTO-892                               | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948           | <input type="checkbox"/> Other _____                                    |

## Office Action Summary

Art Unit: 1646

**DETAILED ACTION**

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, 30-56 and 68-78, drawn to a modified glycoprotein hormone, classified in class 530, subclass 350.
- II. Claim 26, 57-64, drawn to a method of assisting reproduction, classified in class 514, subclass 2.
- III. Claims 27-29, 65-67, drawn to a nucleic acid, vector and a host cell, classified in class 435, subclass 69.1.
- IV. Claims 79-80, drawn to a method of constructing nonchimeric analogs, classified in class 435, subclass 7.1.

B. The inventions are distinct, each from each other because of the following reasons:

Inventions I and II, IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product MPEP § 806.05(h). In the instant case the protein can be used as antigen for antibody production.

Inventions I and III are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acid of invention III can be used to make a hybridization probe, or can be used in gene therapy as well as to produce the protein of interest.

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Inventions III and II, IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and IV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

In addition to the above restriction requirement, Applicant is also required to make an election of species as defined below.

C. This application contains claims directed to the following patentably distinct species of the claimed invention: thyroid-stimulating hormone, follicle-stimulating hormone, luteinizing hormone and chorionic gonadotropin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-11, 24-47, 57, 64-72 and 74-80 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

D. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

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*Advisory information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorraine M. Spector whose telephone number is (703) 308-1793. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lorraine M. Spector, Ph.D.

Patent Examiner

Group 1600

March 22, 2000

*Gary L. Kunz*  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200